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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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TESTA, HURWITZ & THIBEAULT, LLP
HIGH STREET TOWER
125 HIGH STREET
BOSTON, MA 02110

EXAMINER

HARRIS, ALANA M

ART UNIT PAPER NUMBER

1642

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/709,947

Applicant(s)

WATKINS ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-43, 45-48 and 50-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-43, 45-48 and 50-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment and Arguments

1. Claims 41-43, 45-48 and 50-55 are pending.
Claims 41, 43, 45, 48, 54 and 55 have been amended.
Claims 9-20, 44 and 49 have been cancelled.
Claims 41-43, 45-48 and 50-55 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. The information disclosure statement filed March 18, 2003 as Paper number 15 failed to comply with 37 CFR 1.98(a)(2), because of the reasons noted in the first action on the merits (FAOM) mailed September 25, 2003. In response "Applicants note that they intend to file a supplemental IDS including these documents", see Remarks received March 25, 2004.

Withdrawn Objection

Claim Objections

4. The objection of claims 48-55 is withdrawn in light of the claim amendment.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

5. The rejection of claims 9-20 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of the cancellation.
6. The rejection of claims 41, 42, 48 and 50-55 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of claim amendments. Claims 9-20 and 49 have been cancelled.

Claim Rejections - 35 USC § 102

7. The rejection of claims 9-11 and 15-17 under 35 U.S.C. 102(b) as being anticipated by Adams et al. (Cancer Research 43(9): 4297-4301, 1983) is withdrawn in light of the cancellation of the listed claims.

Claim Rejections - 35 USC § 103

8. The rejection of claims 9-20 under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (Cancer Research 43(9): 4297-4301, 1983), and further in view of U.S. Patent Application Publication number 2002/0081659 (March 12, 1999) is withdrawn in light of the cancellation of the listed claims.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 102

9. The rejection of claims 41-43, 45-48 and 50-55 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2002/0081659 (March 12, 1999) is maintained and newly made. Claims 9-20, 44 and 49 have been cancelled.

Applicants argue that the prior art reference is not anticipatory because it is not enabled and Rosen does not describe sequence number 687 as a marker for breast cancer. Applicants aver in detail these two points. Specifically citing the criteria for a proper 35 U.S.C. 102 rejection, setting forth and addressing the Wands factors. These points of view and arguments have been carefully considered but found unpersuasive.

In view of Applicants open language listed in claim 41, "...a protein comprising an amino acid sequence...SEQ ID NO: 1..." the prior art continues to read on Applicants' claims. It is clear that the prior art, U.S. Patent Application Publication #2002/0081659 discloses sequence 687, a protein comprising SEQ ID NO: 1, see attached database sheet mailed with the first office on the merits, September 25, 2003. The intended use of the instantly claimed invention, a kit for detecting the presence of breast cancer or evaluating the efficacy of a therapeutic treatment of a breast cancer is given no patentable weight.

The patent application discloses kits that contain all of the reagents and materials of the claimed invention, see sections 0276-0283. Furthermore, the kit may comprise an isolated polypeptide comprising an epitope, which is specifically immunoreactive with an antibody (i.e. monoclonal, polyclonal and labeled) included in the kit, see sections

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0162, 0271 and 0277. The patent application clearly discloses antibodies that bind the disclosed polypeptide fragment within sequence 687, as well as the sequence itself, see sections 0012, 0211, 0214 and 0267-0270. Detection methods include assaying for the expression of the polypeptide in cells or body fluid in order to assess for breast cancer and ultimately forming complexes in solid support receptacles, see sections 0268, 0351, 0352 and 0545. The diagnostic assay for diagnosing the breast cancer disorder comprises the assaying the expression of the polypeptide of interest in cells, body fluid or serum of an individual using one or more antibodies and the expression level is compared to the standard expression level is indicative of the disorder and furthermore indicative of a comparative reference sample, see sections 0268, 0280, 0313 and 0314.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however can normally be reached between the hours of 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Y. Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

8 June 2004